

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in July 2015.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-565

Trade Name: Thiabendazole, Dexamethasone, Neomycin Sulfate Solution
Pioneer: Tresaderm®
Ingredients: Thiabendazole, dexamethasone, and neomycin sulfate
Sponsor: Putney, Inc.
Approval Date: July 15, 2015
Status: Rx
Route: Topical
Species: Dogs and cats
Drug Form: Solution
Concentration: 40 mg/mL thiabendazole
1 mg/mL dexamethasone
3.2 mg/mL neomycin (from neomycin sulfate)
Indications: As an aid in the treatment of certain bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

ANADA Number: 200-582

Trade Name: Loncor™ 300
Pioneer: Nuflor® Injectable Solution
Ingredients: Florfenicol
Sponsor: Orkeo USA, Inc.
Approval Date: July 9, 2015
Status: Rx
Route: Intramuscular, subcutaneous
Species: Beef and non-lactating dairy cattle
Drug Form: Injectable solution
Concentration: 300 mg/mL
Indications: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteriodes melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

ANADA Number: 200-591

Trade Name: Norfenicol®
Pioneer: Nuflor® Injectable Solution
Ingredients: Florfenicol
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: July 28, 2015
Status: Rx
Route: Intramuscular and subcutaneous injection
Species: Beef and non-lactating dairy cattle
Drug Form: Solution
Concentration: 300 mg/mL
Indications: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteriodes melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

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ANADA Number: 200-553

Trade Name: Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP
Pioneer: Neosporin Ophthalmic Ointment
Ingredients: Neomycin and polymyxin B sulfates, and bacitracin zinc
Sponsor: Akorn Animal Health, Inc.
Approval Date: July 30, 2015
Status: Rx
Route: Ophthalmic
Species: Dogs and cats
Drug Form: Ointment
Concentration: Each gram of ointment contains: polymyxin B sulfate 10,000 units, bacitracin zinc 400 units, and neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base).
Indications: For the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to one or more of the antibiotics contained in the ointment.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-495

Trade Name: Enroflox® 100
Ingredients: Enrofloxacin
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: July 28, 2015

This supplement provides for the addition of new indications, "Single-Dose Therapy: Enroflox® 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*".

NADA Number: 141-216

Trade Name: Quest® Plus Gel
Ingredients: Moxidectin and praziquantel
Sponsor: Zoetis Inc.
Approval Date: July 30, 2015

This supplement supports the safe use in breeding, pregnant, or lactating mares.

Sponsor Change

ANADA Number: 200-366

Previous: IMPAX Laboratories, Inc.
New Sponsor: Putney, Inc.
Drug Labeler Code: 026637

Suitability Petitions

Number: 14-P-0748-0001

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The following corrections or additions to the list were completed in July 2015.

Petitioner: Piedmont Animal Health
Date Filed: June 2, 2014
Action: Approved
Action Date: August 26, 2014
Description: The petitioner requested to file an ANADA for a generic milbemycin oxime that differs from the pioneer product, INTERCEPTOR FLAVOR TABS, sponsored by Novartis Animal Health US, Inc under NADA 140-915. The generic product will differ in dosage form. The RLNAD is approved as a hard compressed tablet. The proposed dosage form is a soft chewable tablet.

Number: 14-P-0772-0001

Petitioner: Piedmont Animal Health
Date Filed: June 6, 2014
Action: Approved
Action Date: August 26, 2014
Description: The petitioner requested to file an ANADA for a generic pimobendan that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The generic product will differ in dosage form. The RLNAD is approved as a compressed, hard, chewable tablet. The proposed dosage form is a soft chewable tablet.

Number: 14-P-0794-0001

Petitioner: e5 Pharma, LLC.
Date Filed: June 12, 2014
Action: Approved
Action Date: August 26, 2014
Description: The petitioner requested to file an ANADA for a generic methimazole that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet. The proposed dosage form is a soft chewable tablet.